# Clinical Trials Data BRAF - Document 12

# Simvastatin and Panitumumab in Treating Patients With Advanced or Metastatic Colorectal Cancer

## Clinical Trial: https://clinicaltrials.gov/study/NCT01110785

"eligibilityCriteria": "DISEASE CHARACTERISTICS:\n\n\* Diagnosis of colorectal cancer\n\n \* Advanced or metastatic disease\n\* Failed prior fluorouracil-, oxaliplatin- and irinotecan-containing regimens\n\n \* In case of progressive disease within 6 months after start of adjuvant fluorouracil-, oxaliplatin-, and irinotecan-containing regimens, the adjuvant therapy is considered to be treatment for metastatic disease\n\* Mutant-type k-ras status (mutation in codon 12, 13, or 61) on tumor material\n\* Measurable disease according to RECIST criteria version 1.1\n\* Progressive disease in the past 3 months according to RECIST criteria version 1.1\n\* No symptomatic brain metastases, defined as any symptoms during the past 6 months\n\nPATIENT CHARACTERISTICS:\n\n\* WHO performance status 0-2\n\* WBC \u2265 2.0 x 10\\^9/L\n\* ANC \u2265 1.5 x 10\\^9/L\n\* Platelet count \u2265 100 x 10\\^9/L\n\* Hemoglobin \u2265 9 g/dL\n\* Serum bilirubin \u2264 1.5 times upper limit of normal (ULN)\n\* AST/ALT \u2264 3 times ULN (\u2264 5 times ULN in case of liver metastases)\n\* Creatinine clearance \u2265 60 mL/min\n\* Magnesium normal\n\* Calcium normal\n\* Creatine phosphokinase \u2264 2.5 times ULN\n\* Not pregnant or nursing\n\* Not planning to become pregnant within 6 months after the end of study treatment\n\* Fertile patients must use highly effective contraception during and for 6 months after completion of study therapy\n\* No noncompliance in previous studies\n\* No alcohol use \\> 4 units/day or unwilling to abstain from use\n\* No history of interstitial lung disease (e.g., pneumonitis or pulmonary fibrosis) or signs of interstitial lung disease on baseline CT scan\n\* No clinically significant cardiovascular disease (including myocardial infarction, unstable angina, symptomatic congestive heart failure, or serious uncontrolled cardiac arrhythmia) \\< 1 year prior to study\n\* No symptomatic hypothyroidism\n\* No history of toxicity during statin use\n\nPRIOR CONCURRENT THERAPY:\n\n\* See Disease Characteristics\n\* No prior EGFr-therapy, including monoclonal antibodies (e.g., panitumumab or cetuximab)\n\* No concurrent verapamil, amiodarone, or dronedarone or unwilling to abstain from use",  
 "healthyVolunteers": false,  
 "sex": "ALL",  
 "minimumAge": "18 Years",  
"stdAges": [  
"ADULT",  
"OLDER\_ADULT"  
]

Question:  
Based on the following clinical trial information, would a patient with a BRAF gene mutation be eligible for the clinical trial?

Answer:  
Based on the provided clinical trial information, a patient's eligibility is primarily determined by specific criteria related to their disease characteristics and medical history. Here, the key points about eligibility concerning genetic mutations are:  
  
- The trial explicitly requires a "mutant-type k-ras status" with a mutation in codon 12, 13, or 61.  
  
The information provided does not mention any eligibility or exclusion criteria related to a BRAF gene mutation. Therefore, the presence or absence of a BRAF mutation does not directly impact eligibility based on the supplied criteria. The patient's BRAF mutation status is not specified as either required or excluded within these criteria.  
  
Thus, a patient with a BRAF gene mutation may still be eligible for this trial, provided they meet all other listed requirements. However, confirmation with the trial coordinators would be advisable to ensure comprehensiveness of trial inclusion and exclusion criteria, including potentially unlisted considerations.